US005879311A

United States Patent [19]

Duchon et al.

[11] **Patent Number: 5,879,311**

[45] **Date of Patent: Mar. 9, 1999**

[54] **BODY FLUID SAMPLING DEVICE AND METHODS OF USE**

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[21] Appl. No.: **857,680**

[22] Filed: **May 16, 1997**

Related U.S. Application Data

[60] Provisional application No. 60/017,133, May 17, 1996, and provisional application No. 60/019,918, Jun. 14, 1996, and provisional application No. 60/023,658, Aug. 1, 1996, and provisional application No. 60/025,340, Sep. 3, 1996.

[51] **Int. Cl.**[6] **A61B 5/00**

[52] **U.S. Cl.** **600/583**; 600/573; 606/181

[58] **Field of Search** 600/573, 576, 600/578, 583; 606/181, 182

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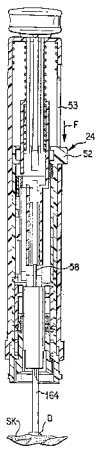
[57] **ABSTRACT**

A device for sampling body fluid includes a housing having a sleeve at a forward end thereof which is displaceable in response to being pressed against a user's skin to trigger the firing of a lancer. After the lancet is removed from the incision, the sleeve is repeatedly pressed against the skin to depress a ring of body tissue in surrounding relationship to the incision to express body fluid outwardly through the incision. A pusher member is then actuated to push a capillary tube through a front end of the housing for drawing-in body fluid. The lancet is a disposable lancet which includes a body supporting a skin-lancing member and the capillary tube. The disposable lancet passes through an upper end of a lancet carrier when being installed or removed. The device cannot be armed until the disposable lancet is installed in the housing, because the capillary tube functions to push a safety device to a non-safety position.

21 Claims, 11 Drawing Sheets



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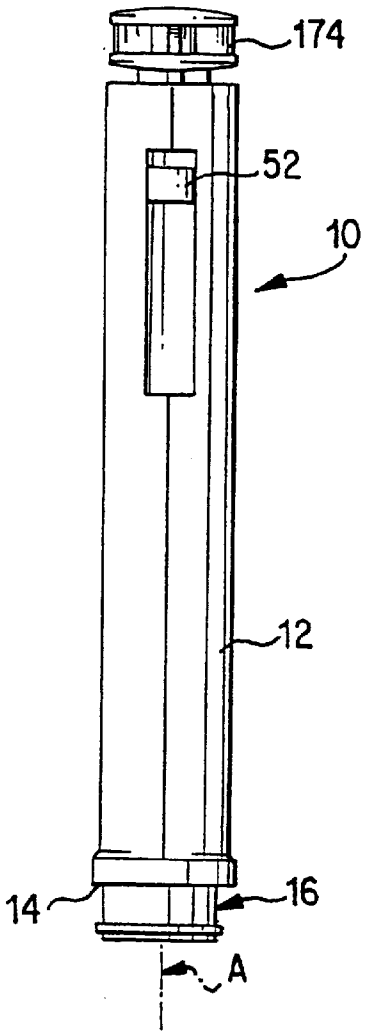
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FIG. 1

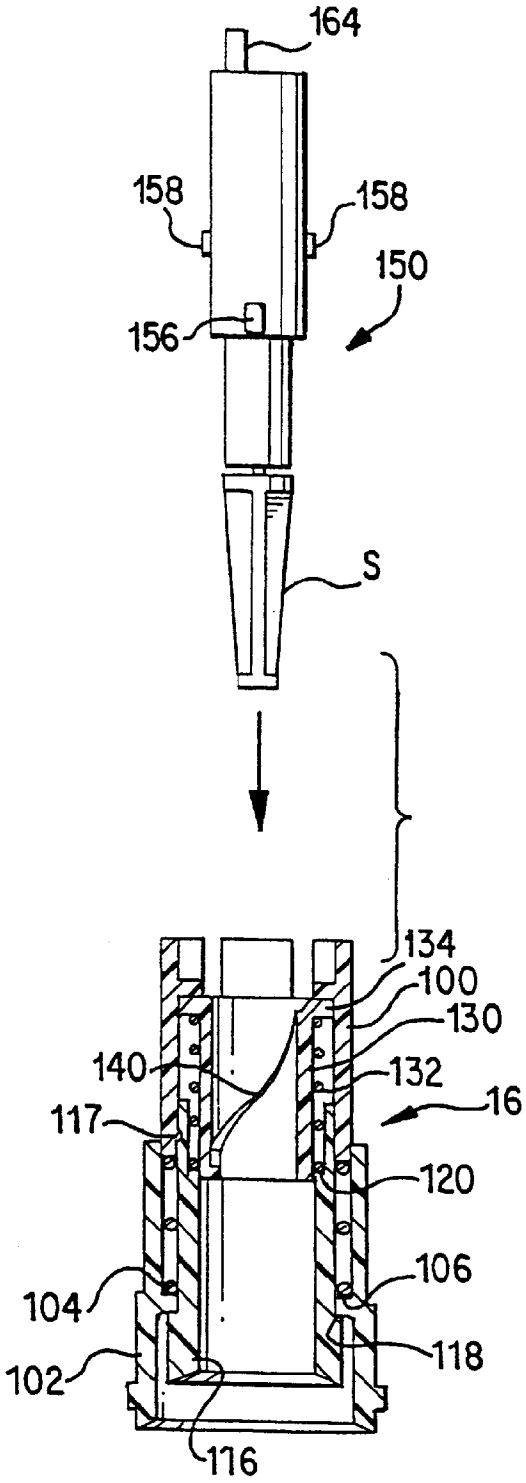
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FIG. 2

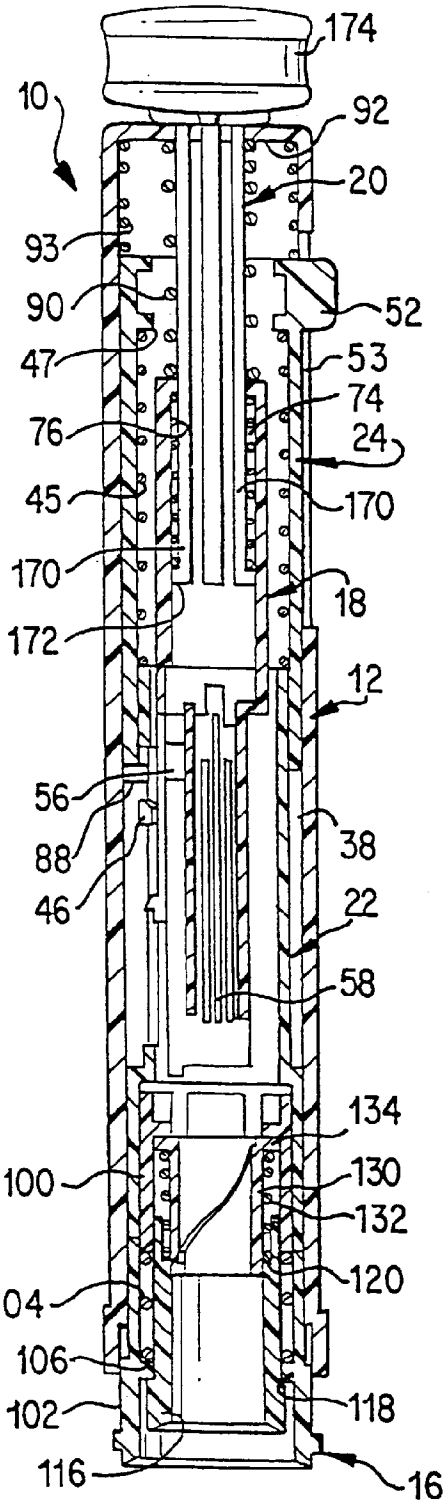
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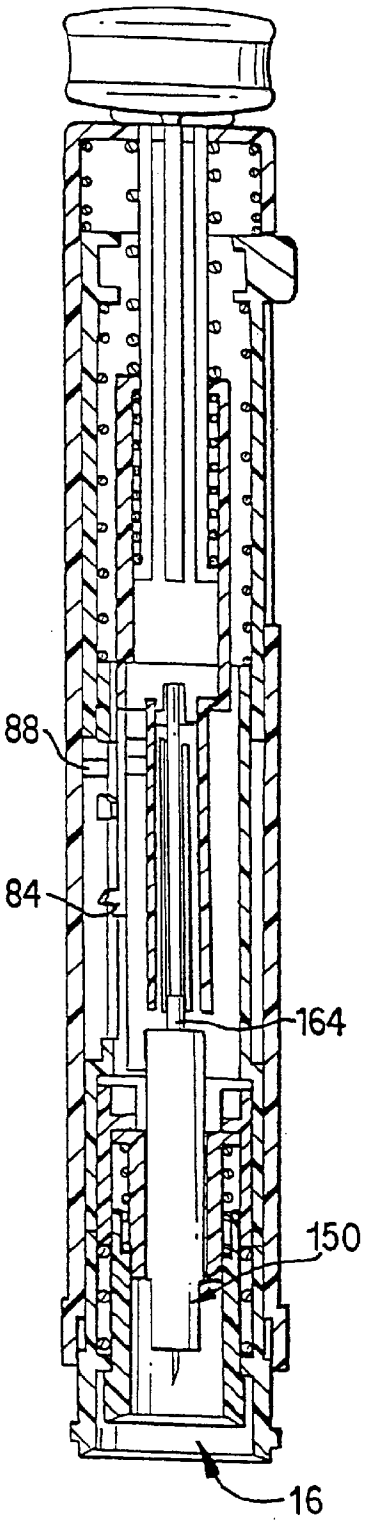
FIG. 3A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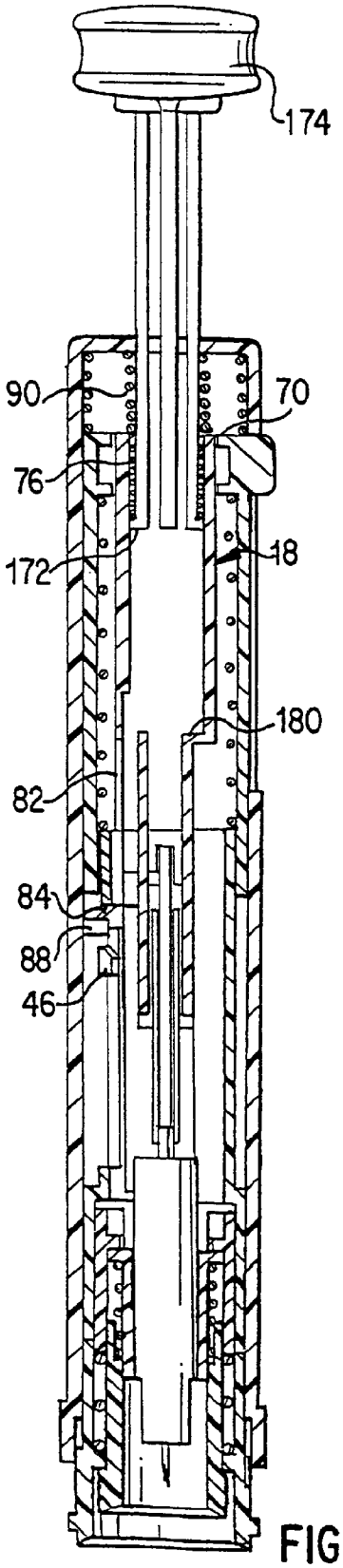

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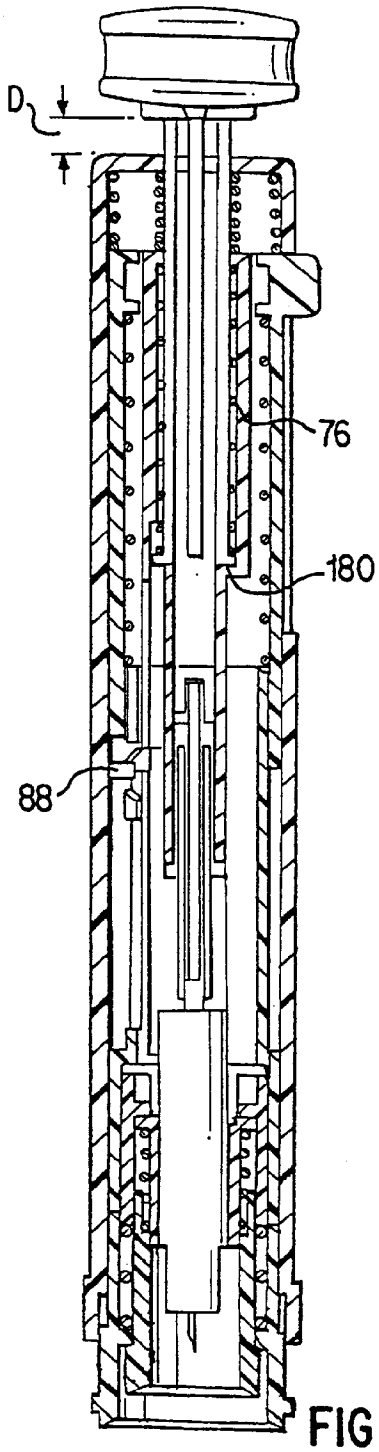

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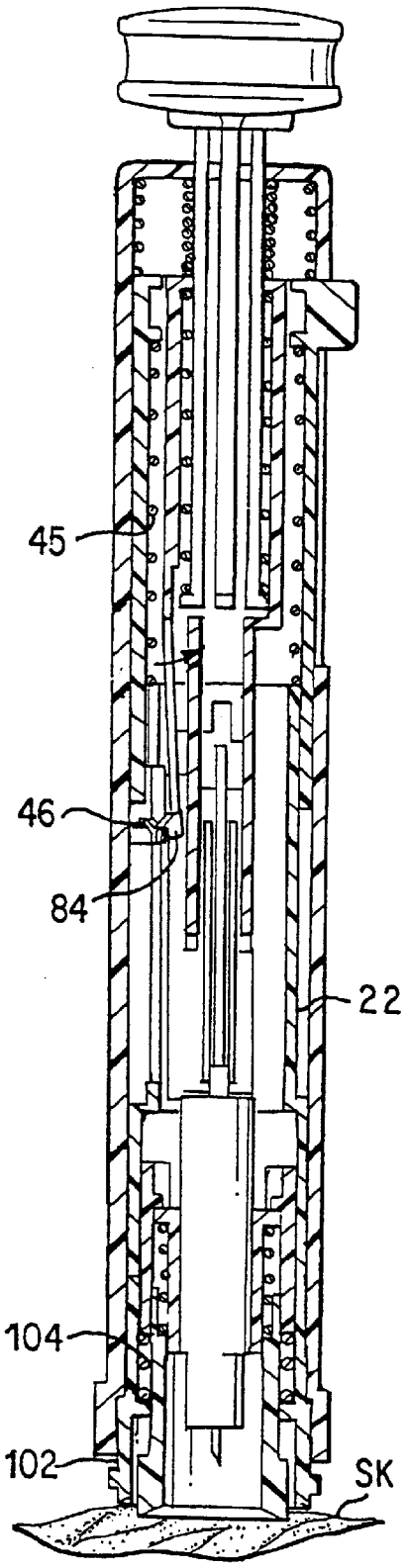

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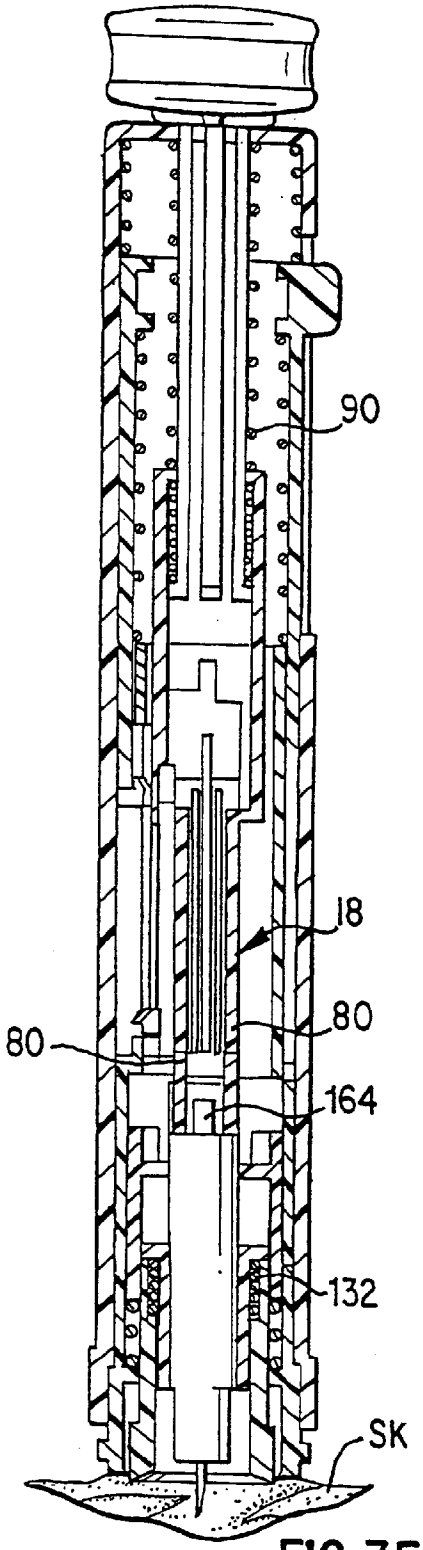

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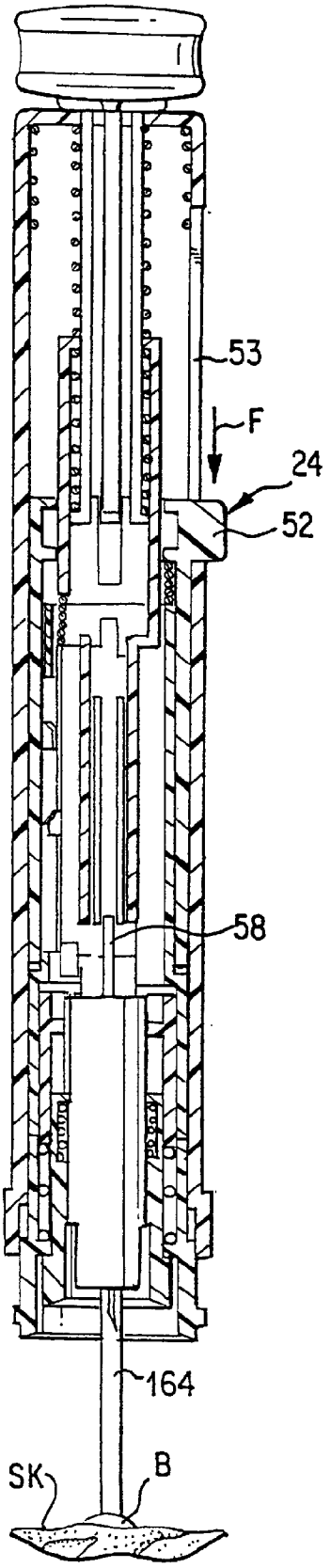

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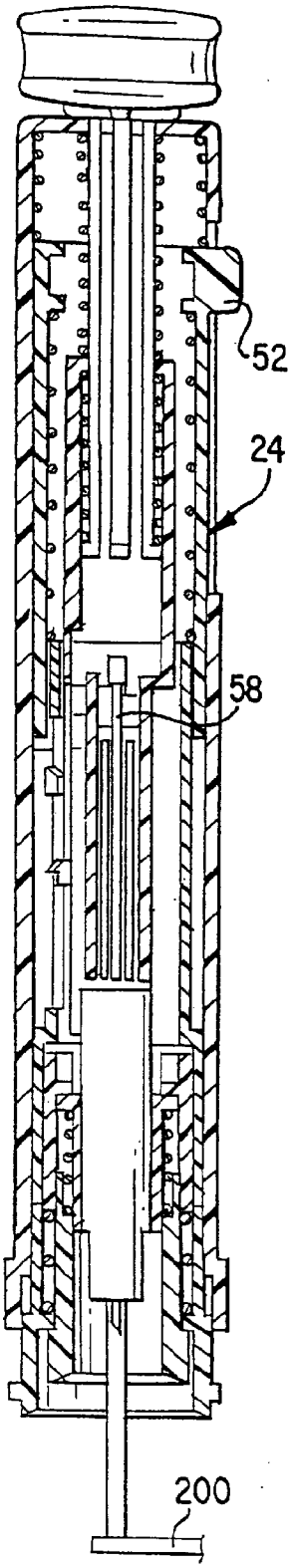

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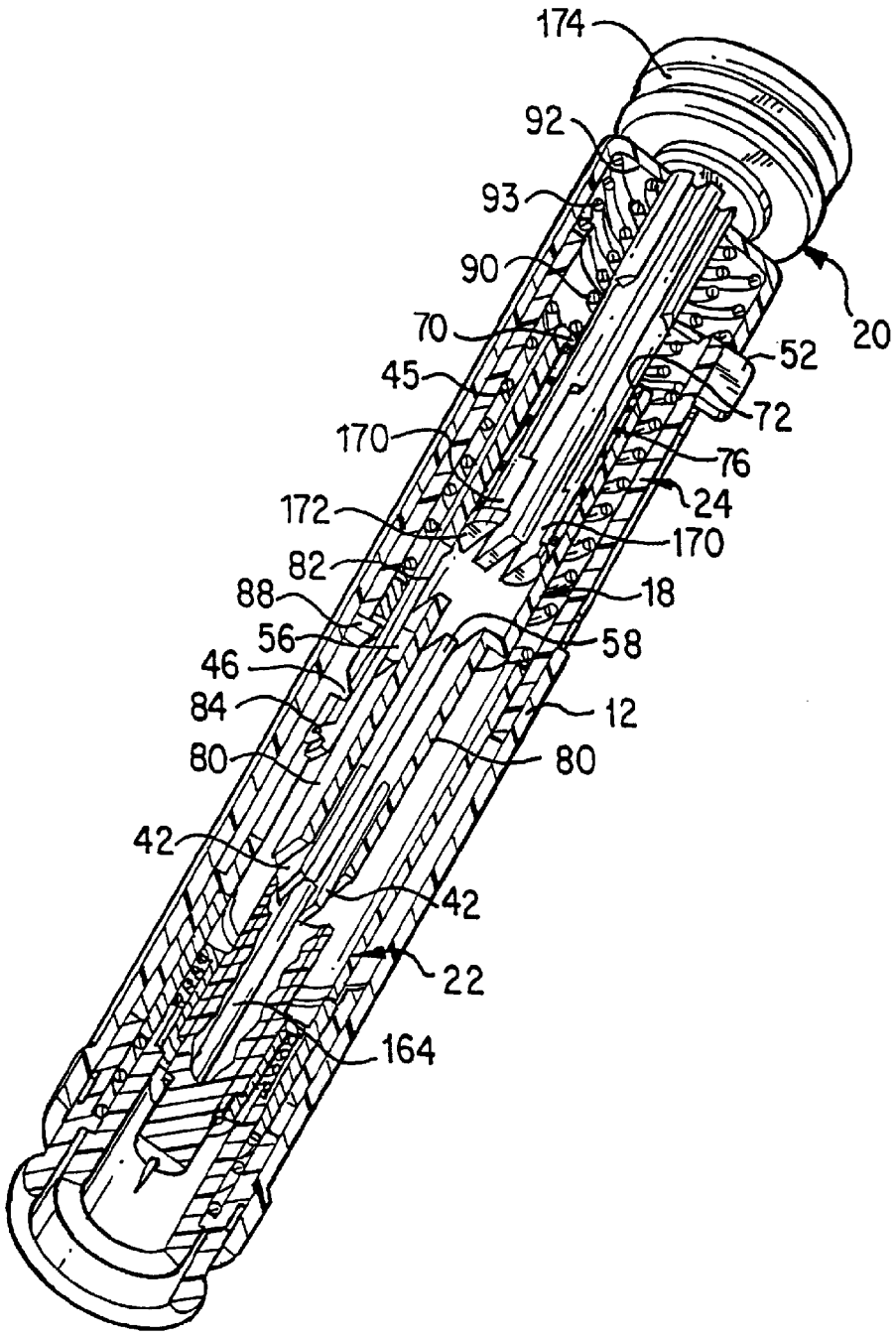
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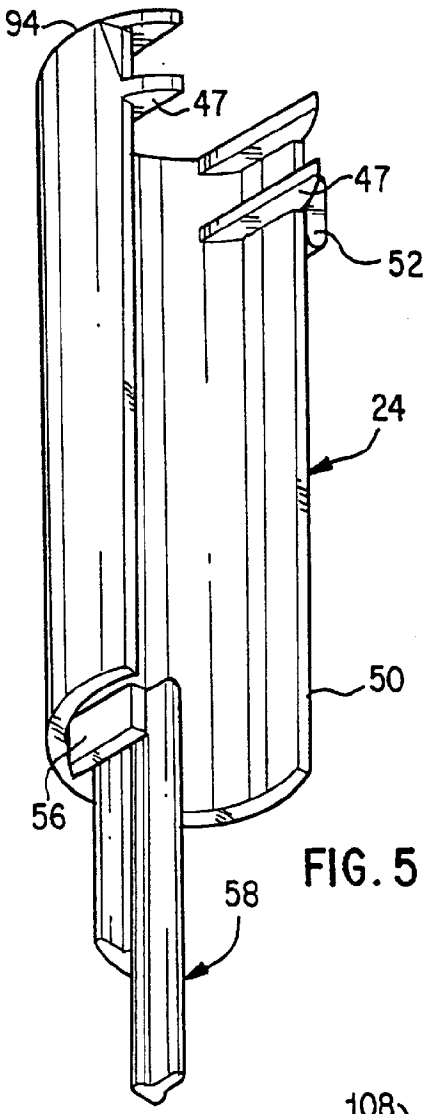
FIG. 4



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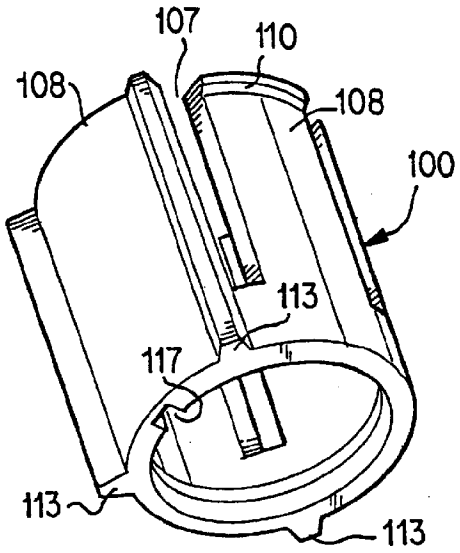
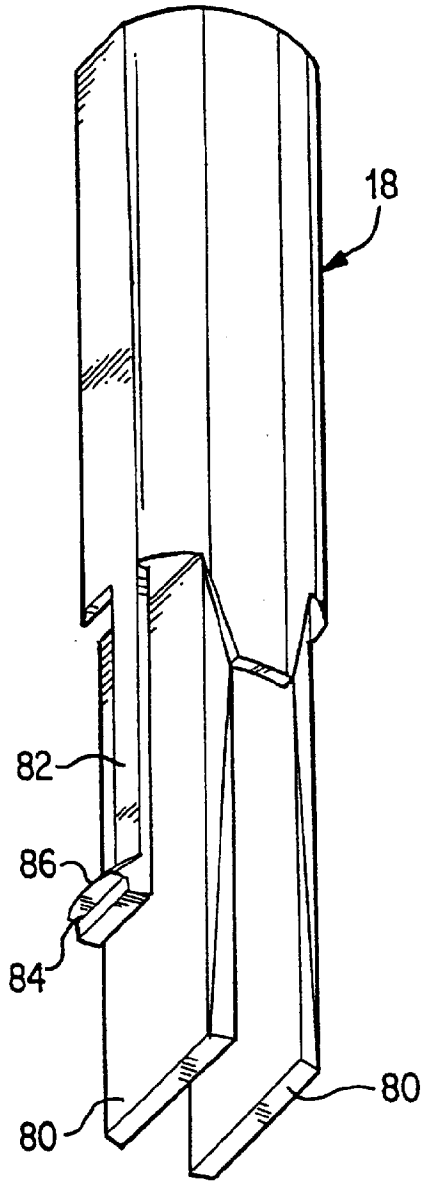


FIG. 6



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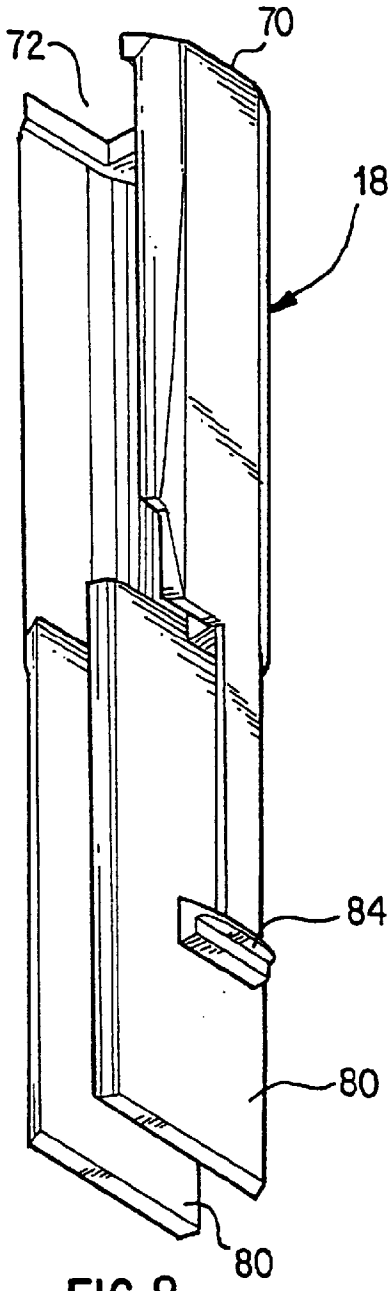

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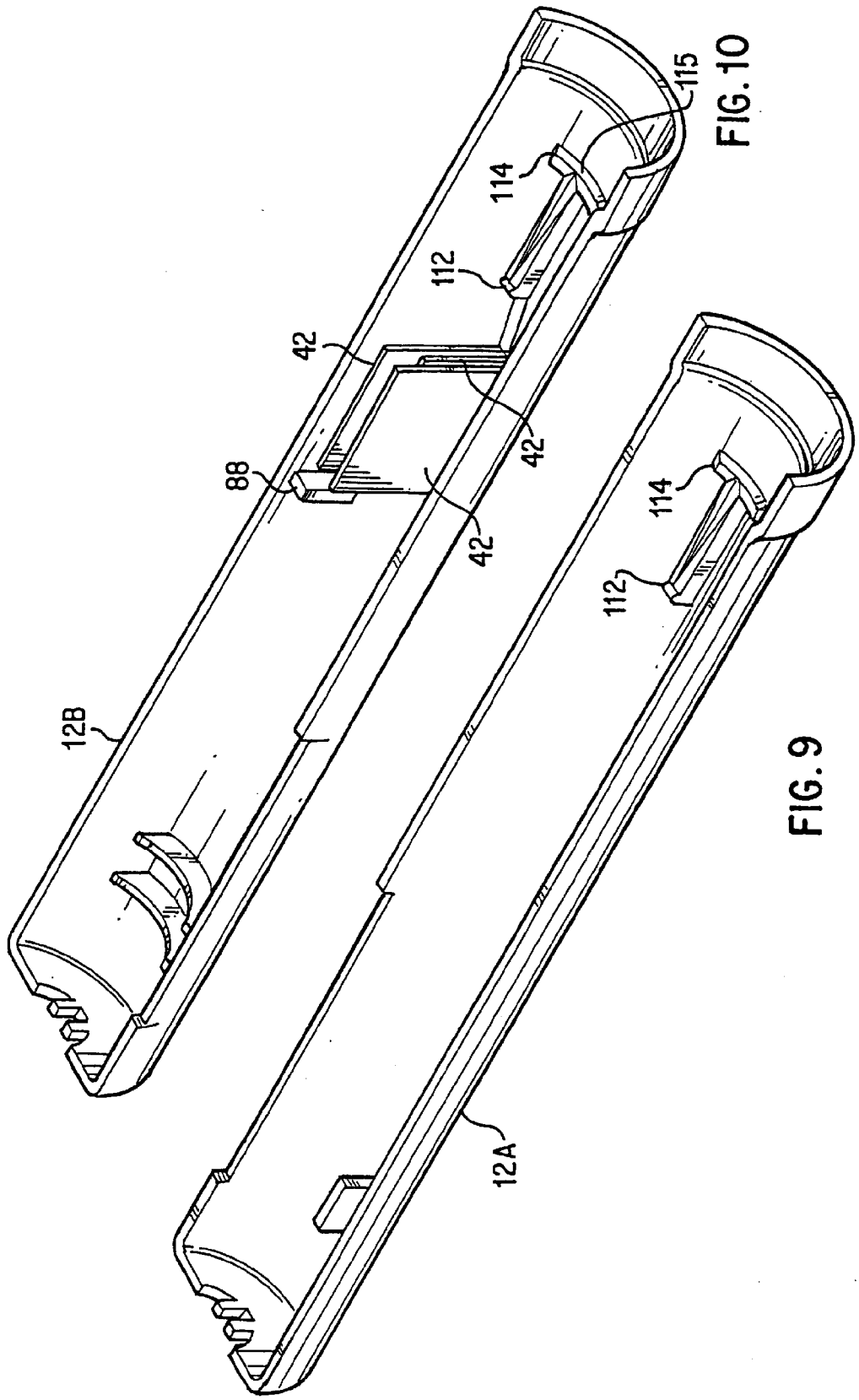

FIG. 10

FIG. 9

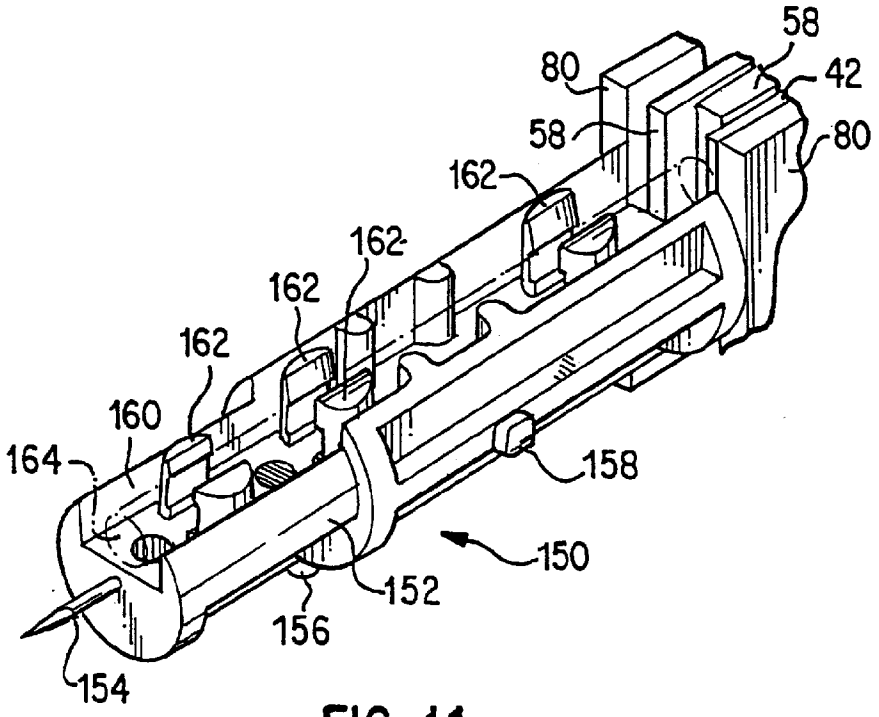
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FIG. 11

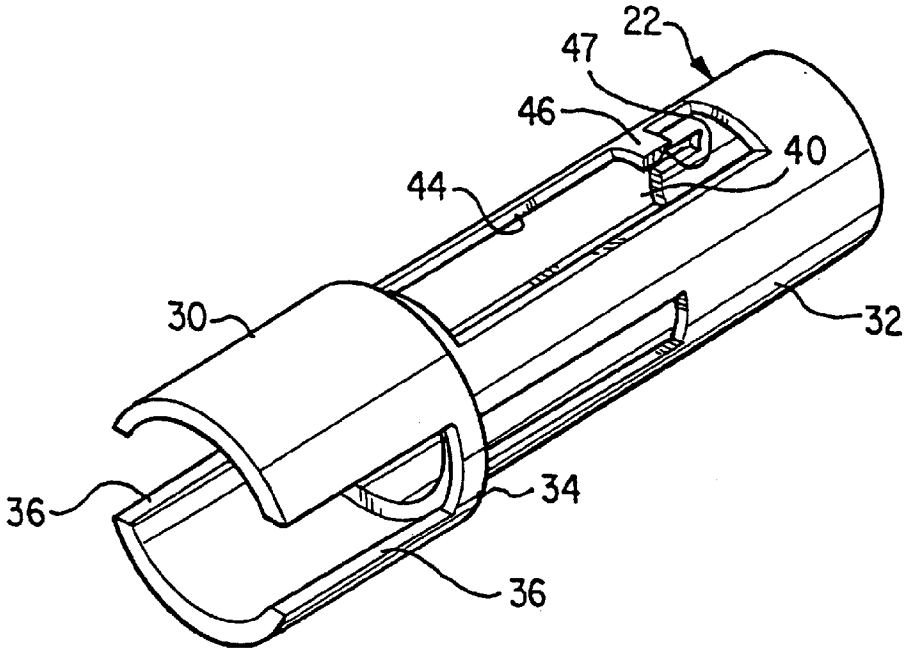
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FIG. 12

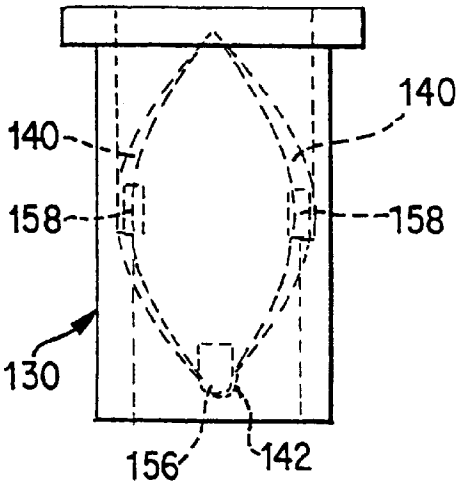

FIG. 13

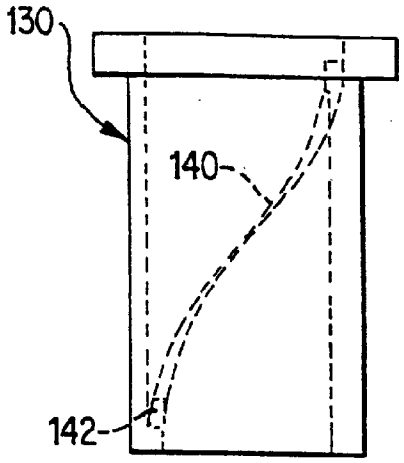

FIG. 14

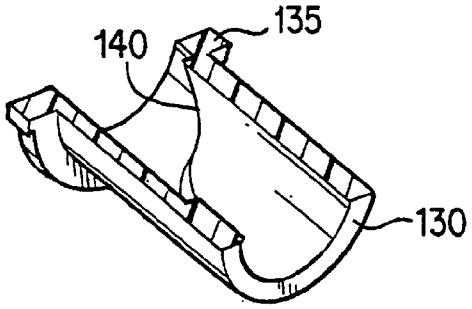

FIG. 15

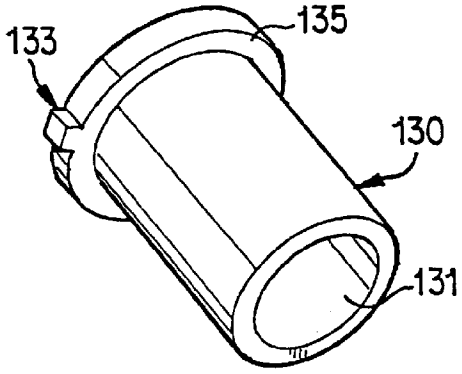

FIG. 16

BODY FLUID SAMPLING DEVICE AND METHODS OF USE

PRIOR APPLICATIONS

This application claims benefit of provisional applications Ser. No. 60/017,133 filed May 17, 1996; 60/019,918 filed Jun. 14, 1996; 60/023,658 filed Aug. 1, 1996; 60/025,340 filed Sep. 3, 1996; 60/714,548 filed Sep. 16, 1996; and 60/710,456 filed Sep. 17, 1996; the disclosures of which are incorporated herein by reference.

The present invention is related to inventions disclosed in the following concurrently filed, commonly assigned U.S. applications: Ser. No. 08/858,045, entitled "Methods and Apparatus For Sampling Body Fluid" (attorney docket no. 018176-057); Ser. No. 08/857,335, entitled "Disposable Element for Use in a Body Fluid Sampling Device" (attorney docket 018176-058); Ser. No. 08/858,042 entitled "Methods and Apparatus for Sampling and Analyzing Body Fluid" (attorney docket 018176-059); Ser. No. 08/858,043, entitled "Methods and Apparatus For Expressing Body Fluid from an Incision" (attorney docket 018176-060) and Ser. No. 08/975,978 entitled "Body Fluid Sampling Device". The disclosures of those applications are incorporated herein by reference.

1. Field of the Invention

The present invention relates to lancing devices and methods for obtaining samples of blood and other fluids from the body for analysis or processing.

2. Background of the Invention

Many medical procedures in use today require a relatively small sample of blood, in the range 5–50 μL. It is more cost effective and less traumatic to the patient to obtain such a sample by lancing or piercing the skin at a selected location, such as the finger, to enable the collection of 1 or 2 drops of blood, than by using a phlebotomist to draw a tube of venous blood. With the advent of home use tests such as self monitoring of blood glucose, there is a requirement for a simple procedure which can be performed in any setting by a person needing to test.

Lancets in conventional use generally have a rigid body and sterile needle which protrudes from one end. The lancet may be used to pierce the skin, thereby enabling the collection of a blood sample from the opening created. The blood is transferred to a test device or collection device. Blood is most commonly taken from the fingertips, where the supply is generally excellent. However, the nerve density in this region causes significant pain in many patients. Sampling of alternate sites, such as earlobes and limbs, is sometimes practiced to access sites which are less sensitive. These sites are also less likely to provide excellent blood samples and make blood transfer directly to test devices difficult.

Repeated lancing in limited surfaces areas (such as fingertips) results in callous formation. This leads to increased difficulty in drawing blood and increased pain.

To reduce the anxiety of piercing the skin and the associated pain, many spring loaded devices have been developed. The following two patents are representative of the devices which were developed in the 1980's for use with home diagnostic test products.

Cornell et al. U.S. Pat. No. 4,503,856 describes a spring loaded lancet injector. The reusable device interfaces with a disposable lancet. The lancet holder may be latched in a retracted position. When the user contacts a release, a spring causes the lancet to pierce the skin at high speed and then retract. The speed is important to reduce the pain associated with the puncture.

Levin et al. U.S. Pat. No. 4,517,978 describes a blood sampling instrument. This device, which is also spring loaded, uses a standard disposable lancet. The design enables easy and accurate positioning against a fingertip so the impact site can be readily determined. After the lancet pierces the skin, a bounce back spring retracts the lancet to a safe position within the device.

In institutional settings, it is often desirable to collect the sample from the patient and then introduce the sample to a test device in a controlled fashion. Some blood glucose monitoring systems, for example, require that the blood sample be applied to a test device which is in contact with a test instrument. In such situations, bringing the finger of a patient directly to the test device poses some risk of contamination from blood of a previous patient. With such systems, particularly in hospital settings, it is common to lance a patient, collect a sample in a micropipette via capillary action and then deliver the sample from the pipette to the test device.

Haynes U.S. Pat. No. 4,920,977 describes a blood collection assembly with lancet and microcollection tube. The device incorporates a lancet and collection container in a single device. The lancing and collection are two separate activities, but the device is a convenient single disposable unit for situations when sample collection prior to use is desirable. Similar devices are disclosed in Sarrine U.S. Pat. No. 4,360,016, and O'Brien U.S. Pat. No. 4,924,879.

Jordan et al. U.S. Pat. No. 4,850,973 and U.S. Pat. No. 4,858,607, disclose a combination device which may be alternatively used as a syringe-type injection device and a lancing device with disposable solid needle lancet, depending on configuration.

Lange et al. U.S. Pat. No. 5,318,584 describes a blood lancet device for withdrawing blood for diagnostic purposes. This invention uses a rotary/sliding transmission system to reduce the pain of lancing. The puncture depth is easily and precisely adjustable by the user.

Suzuki et al. U.S. Pat. No. 5,368,047, Dombrowski U.S. Pat. No. 4,653,513 and Ishibashi et al. U.S. Pat. No. 5,320,607 each describe suction-type blood samplers. These devices develop suction between the lancing site and the end of the device when the lancet holding mechanism withdraws after piercing the skin. A flexible gasket around the end of the device helps seal the end around the puncture site until adequate sample is drawn from the puncture site or the user pulls back on the device.

Garcia et al. U.S. Pat. No. 4,637,403 and Haber et al. U.S. Pat. No. 5,217,480, disclose combination lancing and blood collection devices which use a diaphragm to create a vacuum over the wound site.

Erickson et al. U.S. Pat. No. 5,582,184 describes a means of collecting and measuring body fluids. This system uses a coaxial syringe and capillary tube disposed within a spacer member. The spacer member limits the depth of springe penetration and compresses body tissue around the syringe while the syringe is in the skin, for improving the flow of interstitial fluid to the incision. However, it will be appreciated that the incision will tend to close against the syringe, thereby limiting any advantage that can be achieved.

Single use devices have also been developed for single use tests, i.e. home cholesterol testing, and for institutional use to eliminate cross-patient contamination multi-patient use. Crossman et al. U.S. Pat. No. 4,869,249, and Swierczek U.S. Pat. No. 5,402,798, also disclose disposable, single use lancing devices.

U.S. Pat. Nos. 5,421,816; 5,445,611; and 5,458,140 disclose, as a replacement for invasive sampling, the use of ultrasound to act as a pump for expressing interstitial fluid directly through intact (non-lanced) skin. The amount of fluid which can be obtained in that way is very limited, however.

The disclosures of the above patents are incorporated herein by reference.

Even with the many improvements which have been made, the pain associated with lancing remains a significant issue for many patients. The need for blood sampling and the fear of the associated pain is also a major obstacle for the millions of diagnosed diabetics, who do not adequately monitor their blood glucose due to the pain involved. Moreover, lancing to obtain a blood sample for other diagnostic applications is becoming more commonplace, and less painful, minimally invasive device is needed to enhance those applications and make those technologies more acceptable.

An object of the present invention therefore, is to provide a device and a method for obtaining a sample of bodily fluid through the skin which is virtually pain free and minimally invasive.

Furthermore, known lancing devices include manually actuable buttons for triggering the lance-driving mechanism once the user has placed the device against his/her skin. Because the user knows the precise instant when the lancet will be triggered, there is a tendency for the user to jerk or raise the device at the instant of triggering, which can lead to inconsistent skin penetration, or possibly no penetration. Therefore, a further object of the invention is to provide a lancing device which eliminates such a tendency on the part of the user.

Moreover, known carriers for supporting disposable lancets are configured to permit the disposable lancet member to be inserted and removed solely through a lower end thereof. That requires that a user grasp a lower portion of the disposable lancet member in order to push it upwardly or pull it downwardly. Since the needle projects from a lower end of the disposable lancet member the user's hand will be in the immediate vicinity of the needle, and thus exposed to potential injury and/or contamination. Also, the disposable lancet member is typically held in the carrier by friction fit. Due to normal manufacturing tolerances, it is difficult to ensure a sufficiently tight fit for the disposable lancet member; there may be a tendency for the disposable lancet member to wobble, thereby increasing the amount of pain inflicted during a lancing step.

Therefore, it is another object of the invention to provide a lancet carrier which eliminates the above-mentioned shortcomings.

An additional object of the invention is to make a lancing device safer by preventing the lancet-driving mechanism from being cocked until the disposable has been inserted therein.

Another object of this invention is to provide a method which can result in a sample of either blood or interstitial fluid, depending on the sample site and the penetration depth utilized. While there are no commercially available devices utilizing interstitial fluid (ISF) at this time, there are active efforts to establish the correlation of analytes, such as glucose, in ISF compared to whole blood. If ISF could be readily obtained and correlation is established, ISF may be preferable as a sample since there is no interference of red blood cells or hematocrit adjustment required.

Another object of the invention is to provide a method which can draw a small but adjustable sample, i.e. 3 μL for one test device and 8 μL for another test device, as appropriate.

Another object of this invention is to provide a method by which the drawn sample is collected and may be easily presented to a testing device, regardless of the location of the sample site on the body. This approach helps with infection control in that multiple patients are not brought in contact with a single test instrument; only the sampling device with a disposable patient-contact portion is brought to the test instrument. Alternatively, the disposable portion of a test device may be physically coupled with the sampler so the sample can be brought directly into the test device during sampling. The test device may then be read in a test instrument if appropriate or the testing system can be integrated into the sampler and the test device can provide direct results displayed for the patient.

It is a further object of the invention is to provide a device for minimally invasive sampling comprising a reusable sampler and disposable lancet member, and sample collection device.

SUMMARY OF THE INVENTION

One aspect of the present invention involves a lancing device for lancing skin to sample blood or interstitial fluid. The device comprising a housing. A lancet carrier is mounted adjacent a front end of the housing for longitudinal movement relative thereto. A cockable spring-biased hammer mechanism is provided for pushing the lancet carrier forwardly to lance the skin. A latch is provided for releasable retaining the hammer mechanism in a cocked position. A latch-releasing mechanism includes a skin-contacting portion for being rearwardly displaced in response to being pressed against the skin, and a latch-releasing portion for releasing the latch in response to the rearward displacement of the skin contacting portion.

In another aspect of the invention, a safety mechanism is provided which is normally disposed in a safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safe position in response to installation of the lancet carrier into the housing for enabling the hammer mechanism to be cocked.

In another aspect of the invention, a disposable lancet comprises a body which houses a skin lancing member and a capillary tube. A pusher member is provided for pushing the capillary tube forwardly relative to the body after the skin has been lanced, for drawing-in fluid from the lanced skin.

Yet another aspect of the invention relates to the combination of a disposable lancet and a carrier therefor. The carrier comprises a sleeve adapted to be mounted in a housing. The sleeve includes an internal surface forming a through passage extending from an upper end to a lower end of the sleeve. The disposable lancet is seated in the through passage. The internal surface is configured to permit insertion and removal of the disposable lancet solely through the upper end. The internal surface includes at least one upwardly facing shoulder on which the disposable lancet is supported. The invention also relates to the lancet carrier per se.

Another aspect of the invention relates to a sampling device for sampling body fluid. The sampling device comprises a housing defining a longitudinal axis, and an incision-forming means for forming an incision through the skin surface. A stimulator member is mounted at a forward end of the housing and is depressible against the skin to depress a ring of body tissue in surrounding relationship to the skin for urging body fluid toward and outwardly through the incision, to form a drop of body fluid at an open end of

the incision. A pusher member is provided for moving the capillary tube forwardly relative to the carrier for drawing-in the body fluid.

A method aspect of the invention involves the steps of abutting a forward end of a housing against a skin surface of a user's body, and forming an incision through the skin surface. The housing is pressed against the skin surface to repeatedly depress a ring of body tissue in surrounding relationship to the incision to urge body fluid toward and outwardly through the incision to form a drop of body fluid at an open end of the incision . The capillary tube is extended forwardly relative to the carrier, and a forward end of the capillary tube is inserted into the drop of body fluid.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects and advantages of the invention will become apparent from the following detailed description of a preferred embodiment thereof in connection with the accompanying drawing in which like numerals designate like elements and in which:

FIG. **1** is a side elevational view of a lancing device according to the present invention;

FIG. **2** is a side elevational view of a disposable being inserted into a lancet carrier unit, with the lancet carrier unit being shown in longitudinal section;

FIGS. **3A–3H** are longitudinal sectional views taken through the lancing device and depicting the device in various stages of operation;

FIG. **4** is a longitudinal sectional perspective view of the lancing device according to the invention;

FIG. **5** is a bottom perspective view of a pusher member according to the invention;

FIG. **6** is a bottom perspective view of an adapter member according to the present invention;

FIG. **7** is a bottom perspective view of a hammer member according to the present invention;

FIG. **8** is another bottom perspective view of the hammer member depicted in FIG. **7**;

FIG. **9** is a perspective view of one-half of the housing part according to the present invention;

FIG. **10** is a perspective view of the other housing part according to the invention;

FIG. **11** is a perspective view of a disposable according to the invention, with a capillary tube shown in phantom;

FIG. **12** is a bottom perspective view of an interposer member according to the present invention;

FIG. **13** is a side elevational view of a disposable carrier member according to the present invention, with projections of a disposable shown in phantom lines when the disposable is in an installed condition;

FIG. **14** is a side elevational view, taken from another angle, of the disposable carrier shown in FIG. **13**;

FIG. **15** is a sectional view taken through the carrier member of FIG. **13**; and

FIG. **16** is a bottom perspective view of the carrier of FIG. **13**.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

A minimally invasive sampling device **10** shown in FIG. **1**, includes a tubular housing **12** formed of two half-shells **12A, 12B** (see FIGS. **9** and **10**) that are secured together. The housing **12** defines a longitudinal axis A and a lower open end **14** adapted to receive a removable lancet carrier unit **16**. That carrier unit serves to carry a disposable lancet member **150** (hereinafter a "disposable") and to stimulate a skin puncture site, as will be explained subsequently.

Also mounted in the housing **12** (see FIG. **3A**) are a hammer **18** for displacing the disposable lancet member downwardly in a skin-piercing direction, a manual handle **20** for raising the hammer to a cocked (i.e., downwardly biased) position, an interposer **22** for automatically releasing the hammer in response to a manual pushing of the device against a skin surface, a manually actuable pusher **24** for pushing a blood-receiving capillary tube downwardly, and a plurality of springs for achieving proper placement and movement of the above-described parts.

The interposer **22**, shown in FIGS. **3** and **12**, is longitudinal movable in the housing **12** and includes lower and upper cylindrical portions **30, 32**, the lower portion being of smaller diameter than the upper portion to form an upwardly facing shoulder **34**. A pair of diametrically opposed slits **36** is formed in the lower portion **30** for enabling the carrier unit **16** to be slid upwardly into the housing **12**.

Formed in the upper portion **32** is a slot **40** through which project three longitudinally parallel guide ribs **42** (see FIG. **10**) that are formed integrally with the inner surface of the housing shell **12B**. A center one of the ribs **42** is shorter than the other two ribs **42** to form therewith a space into which an end of a capillary tube **164** can fit, as will be explained. Spaced ninety degrees from the slot **40** is another slot **44**, and formed on a wall of that slot **44** is a triggering protrusion **46** having an inclined upper cam surface **47**, which serves to release the hammer **18** from a cocked position as will be explained.

A coil compression spring **45** is disposed between an upper end of the interposer **22** and shoulders **47** formed on the pusher **24** to bias the interposer **22** downwardly.

The pusher **24**, shown in FIG. **5**, is longitudinally movable and includes a semi-cylindrical portion **50** having a knob **52** projecting radially outwardly from an upper end thereof. The knob **52** is sized to slide along a longitudinal slot **53** formed in the housing **12**. Projecting radially inwardly from a lower end of an inner surface **54** of the portion **50** is a locking rib **56**, and an actuating rib **58**. The locking rib **56** and actuating rib **58** project radially inwardly through the slot **40** formed in the interposer **22**. The actuating rib **58** extends downwardly between the guide ribs **42** of the body **12**, see FIGS. **4** and **11**.

The hammer **18**, shown in FIGS. **7** and **8**, is longitudinally movable in the body **12**, and includes a top wall **70** having an upper opening **72** to enable the handle **20** to be mounted therein. An upper portion **74** of the hammer **18** houses a coil compression spring **76** (see FIG. **3A** which serves as a recovery spring acting between the hammer and the handle **20**, as will be explained. The lower portion of the hammer **18**, comprises a latching arm **82**, and a pair of parallel, longitudinal impact legs **80** which straddle the guide ribs **42** of the body **12**. The latching arm **82** is spaced from one of the legs **80**, to accommodate the locking rib **56** therebetween (see FIGS. **3A** and **4**). The latching arm **82** includes a radial outward finger **84** on its lower end, the top of which is defined by an inclined cam follower surface **86**. As will be explained, the latching arm **82** is flexible in a radial direction when the finger **84** travels vertically past a stop **88** projection which projects radially inwardly from the inner surface of the housing **12** as the hammer is being raised to a cocked position (see FIG. **3E**).

A coil compression spring **90** acts between an upper wall **92** of the body **12** and the top wall **70** of the hammer **18** to

bias the hammer downwardly (see FIG. **3**A). A coil compression spring **93** surrounding the spring **90** acts between the upper wall **92** and an upper edge **94** of the pusher **24** to bias the pusher downwardly.

The carrier unit **16** includes an adapter **100** depicted in FIGS. **2** and **6**. The adapter **100** is generally cylindrical and is telescopingly disposed within a stimulator sleeve **102**. A coil compression spring **104** is interposed between a lower edge of the adapter **100** and an annular flange **106** projecting radially inwardly from an inner surface of the sleeve **102**. The adapter **100** includes a plurality of longitudinal slots **107** dividing the adaptor into a plurality of spring fingers **108**, two of which have a circumferential groove **110** formed in an upper portion thereof. The grooves are configured to receive projections **112** which are formed integrally on inner surfaces of the housing shells **12**A, **12**B, in order to releasable secure the adapter within the housing **12**. That is, if a downward force is applied to the adapter, the spring fingers **108** will yield and permit the adapter to be removed from the housing **12**.

The adapter **100** also includes three radially outwardly projecting keys **113** arranged to engage respective sides **114** of protrusions **115** formed on inner surfaces of the housing shells **12**A, **12**B. The keys **113** and sides **114** are oriented such that the adapter can only enter the housing **12** in one specific circumferential orientation. A longitudinal keyway **117** is formed in an inner surface of the adapter for reasons to be explained.

Telescopingly mounted within the sleeve **102** is an inner ring **116** having a radially outwardly projecting shoulder **118** near its lower end, and a radially inwardly projecting shoulder **120** formed near its upper end. The shoulder **118** is arranged to abut a lower end of the flange **106**. The ring **116** includes an annular recess which receives a radial projection of the adapter **100** to form a snap-in connection **117** therebetween (see FIG. **2**).

Situated coaxially within the adapter **100** and ring **116** is a lancet carrier **130** which is also depicted in FIGS. **13**–**16**. The lancet carrier **130** is generally in the form of a cylindrical sleeve which includes a vertical through-passage **131** to enable a disposable lancet member **150** to be inserted downwardly thereinto when the carrier unit **16** has been removed from the housing **12**. A coil compression spring **132** acts between a radial outer flange **134** of the lancet carrier **130** and radially inner shoulder **120** formed on the ring **116**.

The lancet carrier includes a pair of downwardly inclined, upwardly facing guide ramps **140** formed on its inner surface for guiding the disposable lancet member. Lower ends of the guide ramps **140** intersect to form an upwardly open recess **142**. The ramps and recess form an upwardly facing seat on which the disposable lancet member is supported. A radially outwardly projecting key **133** is formed on an upper annular flange **135** of the carrier **130**. That key **133** enters the keyway **117** if the adapter **100** to orient the carrier **130** circumferentially relative to the adapter.

The disposable lancet member **150** is depicted in FIGS. **2** and **11** and includes a generally cylindrical body **152** having a needle **154** projecting from its lower end. Projecting radially outwardly from an outer periphery of the disposable lancet member **150** are three bosses **156** spaced circumferentially and longitudinally apart. That is, there are provided a lower boss **156**, and a pair of upper bosses **158** disposed at the same elevation above the lower boss. The three bosses are spaced circumferentially apart from one another as the disposable lancet member is viewed in a longitudinal direction. When the disposable lancet member is dropped downwardly into an upper end of the lancet carrier **130** (see FIG. **2**), the two upper projections engage respective ones of the two guide ramps **140** to guide downward motion of the disposable lancet member and ensure that the lower boss **156** enters the recess **142** (see also FIG. **13**).

The disposable lancet member **150** further includes a slot **160** extending longitudinally therealong. Disposed within the slot **160** are plurality of pairs of opposed holding fingers **162** which are configured to frictionally grip the capillary tube **164** and retain the tube **164** in an orientation parallel to the longitudinal axis of the disposable lancet member, as shown in broken lines in FIG. **11**. Due to the cooperation between the projections **156**, **158** of the disposable lancet member and the guide ramps **140** of the lancet carrier **130**, the capillary tube will be positioned in axial alignment with the actuating finger **58** of the pusher **24** when the unit **16** is inserted into the housing **12**, for reasons to be explained.

The handle **20** (FIGS. **3**A and **4**) includes a pair of longitudinally extending lift fingers **170** which project downwardly through the top wall **70** of the hammer **18**. Lower ends of the lift fingers constitute radially outwardly projecting feet **172** against which the lower end of the spring **76** bears. A manually grippable knob **174** is disposed at the top of the handle to enable a riser to raise the handle.

To explain the operation of the lancing device **10**, attention is initially directed to FIG. **3**A which depicts the device **10** in a condition where no disposable lancet member **150** is mounted in the carrier unit **16**. To install a disposable lancet member the carrier unit **16** is pulled downwardly from the housing, and a disposable lancet member **150** is dropped downwardly into the carrier **130** (see FIG. **2**). In so doing, the bosses **156**, **158** of the disposable lancet member ride along the guide ramps **140** of the lancet carrier until the lower boss **156** comes to rest in recess recess **142** of the carrier. As a result, the capillary tube **164** of the disposable lancet member is oriented in a specific relationship with respect to the unit **16**.

The unit **16** is then pushed longitudinally upwardly into the front end of the housing **12** until the grooves **110** formed in the spring fingers **108** of the adapter **100** snap onto the projections **112** of the housing **12**, thereby locking the unit **16** in place (see FIG. **3**B). Due to the relationship between the keys **113** on the adapter, and the sides **115** of the projections **114** formed on the housing **12**, the adapter can be inserted in only one circumferential (rotary) relationship relative to the housing **12**. Furthermore, since the circumferential relationship between the lancet holder **130** and the adapter **100** is pre-set by the engagement between the key **133** on the holder **130** and the keyway **117** on the adapter, it is ensured that the upper end of the capillary tube **164** is aligned with the actuating finger **58** of the pusher **24**. Since the upper end of the capillary tube projects slightly upwardly past the upper end of the disposable lancet member **150** (see FIG. **3**B), it pushes the actuating finger **58**, and thus the entire pusher **24**, slightly upwardly. In so doing, the locking rib **56** of the pusher is raised to a level above the stop **88** of the housing **12** for a reason which will become apparent.

If a protection sheath S covers the needle **154** (see FIG. **2**), it can be pulled off by the user who then grasps the knob **174** of the handle **20** and pulls upwardly thereon (FIG. **3**C). This causes the spring **76** to be compressed between the feet **172** of the raising fingers **170** on the one hand, and the top wall **70** of the hammer **18**. When the spring **76** bottoms out, further raising of the handle **20** causes the hammer **18** to be

raised. Accordingly, the inclined surface **86** on the top of the latching finger **84** sequentially engages the undersides of the triggering protrusion **46** and the stop **88**, causing the latching arm **82** to be flexed radially inwardly and allowing the finger **84** to pass over the protrusion **46** and then over the stop **88**. Eventually, the finger **84** travels past the stop **88** and snaps radially outwardly, whereby downward movement of the finger (and thus of the hammer) is prevented by the top of the stop **88** (FIG. **3**C).

It will be appreciated that had the locking rib **56** not been previously raised, the latching finger could not have been flexed radially inwardly. Therefore, the locking rib **56** ensures that the hammer **18** cannot be placed in an armed or cocked position unless a disposable **150** has been installed.

As the hammer **18** was raised, the spring **90** was simultaneously compressed, so now the hammer **18** is biased downwardly thereby.

When the handle **20** is released, the spring **76** pushes it downwardly (see FIG. **3**D) until the feet **172** of the handle come to rest against a radially inwardly projecting shoulder **180** of the now-raised handle **18**, whereby the knob **174** remains slightly raised by a distance D with respect to its previous position, serving as a visual indication that the hammer is cocked (armed).

When the stimulating sleeve **102** is pushed downwardly against the user's skin (FIG. **3**E), the sleeve **102** becomes displaced upwardly against the bias of the spring **104**, and raises the interposer **22** and its triggering protrusion **46** against the bias of spring **45**. The triggering protrusion **46** is circumferentially offset with respect to the stop **88**, so the protrusion is able to contact the underside of the latching finger **84** and cam it radially inwardly off the stop **88**. This enables the previously-compressed spring **90** to displace the hammer **18** and its impact legs **80** downwardly opposite the bias of the spring **76** and against the disposable lancet member **150** (FIG. **3**F), to push the disposable lancer member **150** and the carrier **130** downwardly opposite the bias of the spring **132**, whereby the needle lances the skin. The carrier **130** and the disposable lancet member **150** are immediately withdrawn upwardly by the action of the spring **132**. Such withdrawal is possible since the hammer **18** was immediately retracted by the spring **76**. Thus, the lancing and retraction of the lancet is performed as a substantially continuous motion.

Next, the user repeatedly reciprocates the housing **12** up and down, whereby the stimulating sleeve **102** remains in contact with the skin but repeatedly pressured by the spring **45** and repeatedly opens and closes the wound in a manner pumping fluid (such as blood) to the skin surface in the manner described in greater detail in Application Ser. No. 08/858,043 (attorney docket 018176-060), the disclosure of which is incorporated by reference herein.

That is, each time that a downward force is applied, the end face of the outer stimulating sleeve exerts a downward force which depresses a ring-shaped portion of the skin and body tissue which is disposed in surrounding relationship to the wound or incision I, causing the wounded area to bulge while pulling apart the sides of the wound. Hence, fluid such as blood or interstitial fluid is trapped and pressurized so that it travels upwardly through the pulled-open end of the bulging wound since the surrounding ring of depressed skin and body tissue restricts the outward flow of fluid.

When the downward force is released, the sides of the wound close, and fresh fluid flows toward the area of the wound to replace fluid which had been forced upwardly through the wound. As the downward force is reapplied, the above-described action is repeated and additional fluid is forced through the wound. Eventually, this "pumping" action results in the formation of a suitably large drop B of body fluid.

Although the end face of the sleeve **102** is disclosed as being generally annular, it could be of other configuration such as oval or polygonal, whereby the ring of depressed body tissue would be similarly configured.

When a sufficiently large drop of fluid B has been developed at the skin surface (FIG. **3**G), the user applies a downward force F to the knob **52** of the pusher **24** to displace the pusher and its actuating rib **58** downwardly against the bias of the spring **38**. This pushes the capillary tube **164** downwardly until the lower end thereof projects from the bottom of the housing **12**. At that point, the lower end of the capillary tube is placed in the drop of blood to draw blood thereinto by capillary action. The pusher **24** can be released, whereupon it will be displaced upwardly by the spring **38**.

Then, a strip of material **200** can be brought into contact with bottom of the capillary tube (FIG. **3**H) to draw-out the fluid sample for analysis.

To perform a subsequent lancing/sampling operation, the user grasps the sleeve **102** and pulls out the carrier unit **16**. The disposable lancet member **150** can then be lifted from the carrier **130** and discarded, whereupon a new disposable lancet member can be inserted.

Except for the needle **154** and the springs **93**, **90**, **45**, **76**, **104** and **132**, the parts of the lancing device **10** are preferably formed of plastic.

It will be appreciated that the device **10** provides for an automatic triggering of the hammer in response to a pressing of the device against the skin. This eliminates any tendency for the user to jerk the device upwardly at the instant of triggering and ensures that penetrations of constant depth will be performed from one lancing operation to the next.

The ability of the device to prevent the hammer from being cocked unless a disposable lancet member has been installed provides assurance that the disposable lancet member will not be accidentally displaced forwardly as the carrier unit is being installed, as could otherwise occur if the hammer were in a cocked state during such installation. Hence, the user is protected against an accidental wounding.

The ability of the device to push-out the capillary tube for talking-in a fluid sample simplifies the sampling operation and minimizes the amount of direct manual handling of the capillary tube which is required. In fact, no direct contact with that tube need occur when using the device. This feature of the invention does not require the use of a lancet for making the incision. In lieu of using a lancet to make an incision, known pneumatic or hydraulic injectors of the type which inject pressurized gas or liquid against the skin could be used. Such auto injectors are sold by Becton-Dickinson, for example, to inject insulin. By eliminating the insulin and merely injecting the gas (e.g., air or nitrogen) or liquid (e.g., water) at pressures above 30 psi. an incision could be formed in the skin for taking samples of body fluid. Advantageously, small particles could be mixed with the gas to promote the tissue-cutting action. The particles could comprise carbon particles of from 1 micron to 0.010 inches in diameter.

The ability to load and unload a disposable lancet member into the carrier unit through an upper end of that unit means that the user can keep his/her hands remote from the needle. This ensures against accidental wounding, possibly by a contaminated needle. The three-point securement of the disposable lancet member within the carrier, as defined by the three projections of the disposable, creates a stable

movement-free mounting of the disposable lancet member within the carrier unit. Hence, the disposable lancet member will not tend to move laterally during a lancing procedure, thereby reducing recess amount of pain that may be experienced by the user.

Also, as explained in concurrently filed application Ser. No. 08/858,043 (attorney docket 018176-060), the ability of the device to pump body fluids such as blood or interstitial fluid to the skin surface enables the device to be used to lance the skin at areas of the body which are less susceptible to pain, such as the arm for example.

Although the present invention has been described in connection with a preferred embodiment thereof, it will be appreciated by those skilled in the art that additions, modifications, substitutions and deletions not specifically described may be made without departing from the spirit and scope of the invention as defined in the appended claims.

What is claimed is:

1. A lancing device for lancing the skin to sample blood or interstitial fluid, comprising:

a housing;

a lancet carrier carrying disposable lancet member, the disposable lancet member includes a body holding a skin lancing member, a capillary tube, and a pusher member for pushing the capillary tube forward relative to the carrier for drawing-in fluid from the lanced skin, the carrier mounted adjacent a front end of the housing for movement relative thereto;

a cockable spring-biased hammer mechanism for displacing the lancet carrier forwardly to lance the skin;

a latch for releasably retaining the hammer mechanism in a cocked position; and

a latch-releasing mechanism including a skin-containing portion for being rearwardly displaced in response to being pressed against the skin, and a latch-releasing portion for releasing the latch in response to the rearward displacement of the skin-contacting portion.

2. The lancing device according to claim **1** wherein the skin-contacting portion comprises a sleeve mounted at the front end of the housing, the sleeve being spring-biased forwardly and being displaceable rearwardly in response to being pressed against the skin, to cause the latch-releasing portion to release the latch.

3. The lancing device according to claim **1**, further comprising a safety device normally disposed in a safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safety position in response to installation of the lancet carrier into the housing for enabling the hammer mechanism to be cocked.

4. The lancing device according to claim **3**, wherein the safety device is moved to its non-safety position by an upper end of the capillary tube within the lancet carrier.

5. The lancing device according to claim **4**, wherein the lancet carrier comprises a sleeve mounted in the housing; the sleeve including an internal surface forming a through-passage extending from an upper end to a lower end of the sleeve; a disposable lancet seated in the through-passage; the internal surface configured to permit insertion and removal of the disposable lancet solely through the upper end; the internal surface including at least one upwardly facing seat on which the disposable lancet is supported.

6. The lancing device according to claim **3**, wherein the lancet carrier comprises a sleeve mounted in the housing; the sleeve including an internal surface forming a through-passage extending from an upper end to a lower end of the sleeve; a disposable lancet seated in the through-passage; the internal surface configured to permit insertion and removal of the disposable lancet solely through the upper end; the internal surface including at least one upwardly facing seat on which the disposable lancet is supported.

7. The lancet device according to claim **1**, wherein the lancet carrier comprises a sleeve mounted in the housing; the sleeve including an internal surface forming a through-passage extending from an upper end to a lower end of the sleeve; a disposable lancet seated in the through-passage; the internal surface configured to permit insertion and removal of the disposable lancet solely through the upper end; the internal surface including at least one upwardly facing seat on which the disposable lancet supported.

8. The lancing device according to claim **1** wherein the skin contacting portion includes a sleeve structure mounted for repeated rearward displacements to urge body fluid from lanced skin.

9. The lancing device according to claim **8** wherein the skin contacting portion is shaped to form a depressed ring of body tissue in surrounding relationship to an incision formed in the skin.

10. The lancing device according to claim **9**, further including a safety device normally disposed in a safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safety position in response to installation of the lancet carrier into the housing for enabling the hammer mechanism to be cocked.

11. A lancing device for lancing skin to sample blood or interstitial fluid, comprising:

a housing;

a lancet carrier carrying a disposable lancet member, the disposable lancet member includes a body holding a skin lancing member, a capillary tube, and a pusher member for pushing the capillary tube forward relative to the carrier for drawing-in fluid from the lanced skin, the carrier installable into a front end of the housing and being movable relative thereto;

a cockable spring-biased hammer mechanism for displacing the lancet carrier forwardly to lance the skin;

a latch-releasing mechanism for releasing a latch; and

a safety device normally disposed in a safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safety position in response to installation of the lancet carrier into the housing for enabling the hammer mechanism to be cocked.

12. The lancing device according to claim **11**, wherein the lancet carrier comprises a sleeve mounted in the housing; the sleeve including an internal surface forming a through-passage extending from an upper end to a lower end of the sleeve; a disposable lancet seated in the through-passage; the internal surface configured to permit insertion and removal of the disposable lancet solely through the upper end; the internal surface including at least one upwardly facing seat on which the disposable lancet is supported.

13. A lancing device for lancing skin to sample blood or interstitial fluid, comprising:

a housing;

a carrier carrying a disposable lancet member, the disposable lancet member including a body having a skin-lancing member and a capillary tube; a spring-biased hammer for pushing the carrier so that the lancet lances the skin; and

a pusher member for pushing the capillary tube forwardly relative to the carrier for drawing-in fluid from lanced skin.

14. The lancing device according to claim **13**, wherein the carrier comprises a sleeve mounted in the housing; the

sleeve including an internal surface forming a through-passage extending from an upper end to a lower end of the sleeve; the internal surface configured to permit insertion and removal of the disposable lancet solely through the upper end; the internal surface including at least one upwardly facing seat on which the disposable lancet is supported.

15. A lancet carrier adapted to carry a disposable lancet, the lancet carrier comprising a sleeve to be mounted in a housing, the sleeve including an internal surface forming a through-passage extending from an upper end to a lower end of the sleeve and configured to permit insertion and removal of a disposable lancet solely through the upper end, the internal including an upwardly facing seat adapted to support a disposable lancet, the seat includes a plurality of upwardly facing shoulders having a pair of downwardly inclined ramps and a slot disposed below the ramps, the lancet including vertically spaced projections extending outwardly therefrom and bearing against respective ones of the upwardly facing shoulders.

16. A sampling device for sampling body fluid, comprising:

a housing defining a longitudinal axis;

incision-forming means mounted in the housing for forming an incision through a skin surface;

a stimulator member mounted at a forward end of the housing and being depressible against the skin to depress a ring of body tissue in surrounding relationship to the skin for urging body fluid toward and outwardly through the incision to form a drop of body fluid at an open end of the incision;

a capillary tube; and

a pusher member for moving the capillary tube forwardly within the housing for drawing-in the body fluid.

17. The lancing device according to claim **16** wherein the incision forming means comprises:

a lancet carrier carrying a disposable lancet, the lancet including a skin-lancing member and a capillary tube, the lancet carrier mounted adjacent a front end of the housing for longitudinal movement relative thereto; and

means for driving the lancet carrier forwardly and then rearwardly in a substantially continuous motion to form an incision through the skin surface and retract the lancet from the incision.

18. The lancing device according to claim **17**, further including a cockable spring biased hammer mechanism in the housing for displacing the lancet carrier forwardly; and a safety device disposed in the housing normally in a safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safety position by a rear end of the capillary tube.

19. A method of taking a sample of body fluid, comprising the steps of:

A) abutting a forward end of a housing against a skin surface of a user's body;

B) forming an incision through the skin surface;

C) pressing the housing against the skin surface a plurality of times to repeatedly depress a ring of body tissue in surrounding relationship to the incision to urge body fluid toward and outwardly through the incision to form a drop of body fluid at an open end of the incision;

D) extending the capillary tube forwardly relative to the carrier; and

E) inserting a forward end of the capillary tube into the drop of body fluid to draw-in the body fluid.

20. The method according to claim **19** wherein step A comprises abutting the housing against a surface of the user's body other than a finger tip thereof.

21. The method according to claim **19** wherein step A comprises abutting the housing against the user's forearm.

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